TOP CALIBRE SDN. BHD. K123819

MAR 0 5 2013

FDA 510(k), Premarket Notification: 510(k) Summary of Safety and Effectiveness Information

Date: 01 March 2013

1.0 Submitter:

Top Calibre Sdn Bhd
1-1, 2, Jalan Setia Prima U13/S
Setia Alam, Seksyen U13,
40170 Shah Alam, Selangor,
Malaysia

Telephone No.: +603 3291 0516
Fax No.: +603 3291 0542

2.0 Contact Person:

Contact: Ms Rosnita Maodin
Telephone No.: +603 3291 0516
Fax No.: +603 3291 0542

3.0 Name of Device:

Trade Name: Powder Free Latex Patient Examination Glove, Blue, Tested for Use with Chemotherapy Drugs, with Protein Content Labeling Claim (Contains 50 Micrograms per dm^2 of glove or Less of Water Extractable Protein)
Common Name : Patient Examination Glove
Classification Name : Patient Examination Glove
Regulation Number : 21 CFR 880.6250
Classification Number: Class I
Product Code : 80 LYY, 80 LZC

4.0 Identification of the Legally Marketed Device:

Powder Free Latex Patient Examination Glove, Blue, Tested for Use with Chemotherapy Drugs, with Protein Content Labeling Claim (Contains 50 Micrograms per dm^2 of glove or Less of Water Extractable Protein), Class I patient examination gloves, Latex – 80 LYY, Specialty – 80 LZC, meets all of the requirements of ASTM D3578-05 (2010) Standard Specification for Rubber Examination Glove.

Predicate Device: K083409, Powder Free Blue Latex Patient Examination Glove, Tested for use with Chemotherapy Drugs with a Protein Content Label Claim ($\leq$50 ug/dm^2 per glove of Extractable Protein).

5.0 Description of Device:

Powder Free Latex Patient Examination Glove, Blue, Tested for Use with Chemotherapy Drugs, with Protein Content Labeling Claim (Contains 50 Micrograms per dm^2 of glove or Less of Water Extractable Protein) meets all the current specification for ASTM D3578-05 (2010).
The gloves are non-sterile, ambidextrous and single-use disposable devices that come in five sizes (XS, S, M, L, XL).

6.0 Intended Use of the Device:

A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.
This glove has been tested for use with specific chemotherapy drugs listed below.

Chemotherapy Drug Permeation (Minimum Breakthrough Detection Time in Minutes)

Carmustine (BCNU) (3.3 mg/ml)	**15.4**
Cisplatin (1.0 mg/ml)	> 240
Cyclophosphamide (Cytoxan) (20.0 mg/ml)	> 240
Cytarabine (100 mg/ml)	> 240
Dacarbazine (DTIC) (10.0 mg/ml)	> 240
Doxorubicin Hydrochloride (2.0 mg/ml)	> 240
Etoposide (20.0 mg/ml)	> 240
Fluorouracil (50.0 mg/ml)	> 240
Ifosfamide (50.0 mg/ml)	> 240
Methotrexate (25 mg/ml)	> 240
Mitomycin C (0.5 mg/ml)	> 240
Mitoxantrone (2.0 mg/ml)	> 240
Paclitaxel (Taxol) (6.0 mg/ml)	> 240
Thiotepa (10.0 mg/ml)	**30.6**
Vincristine Sulfate (1.0 mg/ml)	> 240

Please note that the following drugs - Carmustine and Thiotepa have extremely short permeation times of 15.4 and 30.6 minutes, respectively.

7.0 Summary of the Technological Characteristics of the Device:

Powder Free Latex Patient Examination Glove, Blue, Tested for Use with Chemotherapy Drugs, with Protein Content Labeling Claim (Contains 50 Micrograms per dm^2 of glove or Less of Water Extractable Protein) possesses the following technological characteristic (as compared to ASTM or equivalent standards):

Characteristic	Standards Requirements	Results Summary			Conclusions
Dimensions	ASTM D 3578-05 (2010)	Length		≥ 270mm	Meets Standard Requirements
		Palm Thickness		≥ 0.20mm	
		Finger Thickness		≥ 0.25mm	
		Width	X-Small	70-80mm	
			Small	80-90mm	
			Medium	90-100mm	
			Large	101-111mm	
			X-Large	≥ 111mm	
Physical Properties	ASTM D 3578-05 (2010)		Before Aging	After Aging	Meets Standard Requirements
		Tensile Strength	≥ 18 MPA	≥ 14 MPA	
		Elongation	≥ 650%	≥ 500%	
Freedom from pinholes	ASTM D 5151-11 ASTM D 3578-05 (2010)	Tested in accordance with ASTM D5151 test method. Pass quality level at G1 AQL 1.5			Meets Standard Requirements
Powder Free Residue	ASTM D 6124-11 ASTM D 3578-05 (2010)	Result generated values ≤ 2 mg of residual powder per glove			Meets Standard Requirements
Protein Content	ASTM D 5712-10 ASTM D 3578-05 (2010)	Result generated values ≤ 50 microgram/dm^2			Meets Standard Requirements
Biocompatibility	Dermal Sensitization (as ISO 10993-10:2010)	Not a contact skin sensitizer			Meets Standard Requirements
	Primary Skin Irritation Test (as ISO 10993-10:2010)	Not a primary skin irritant			Meets Standard Requirements
Chemotherapy Drugs Permeation Test Method	ASTM D6978-05	Chemotherapy Drug Permeation (Minimum Breakthrough Detection Time in Minutes)			Tested for Use with Chemotherapy Drugs. Carmustine and Thiotepa have extremely short permeation times of 15.4 and 30.6 minutes, respectively.
		Carmustine (3.3 mg/ml)		**15.4**	
		Cisplatin (1.0 mg/ml)		>240	
		Cyclophosphamide (20.0 mg/ml)		>240	
		Cytarabine (100 mg/ml)		>240	
		Dacarbazine (DTIC) (10.0 mg/ml)		>240	
		Doxorubicin Hydrochloride (2.0 mg/ml)		>240	
		Etoposide (20.0 mg/ml)		>240	
		Fluorouracil (50.0 mg/ml)		>240	
		Ifosfamide (50.0 mg/ml)		>240	
		Methotrexate (25 mg/ml)		>240	
		Mitomycin C (0.5 mg/ml)		>240	
		Mitoxantrone (2.0 mg/ml)		>240	
		Paclitaxel (Taxol) (6.0 mg/ml)		>240	
		Thiotepa (10.0 mg/ml)		**30.6**	
		Vincristine Sulfate (1.0 mg/ml)		>240	

8.0 Substantial Equivalent Based on Assessment of Non-Clinical Performance Data

Powder Free Latex Patient Examination Glove, Blue, Tested for Use with Chemotherapy Drugs, with Protein Content Labeling Claim (Contains 50 Micrograms per dm^2 of glove or Less of Water Extractable Protein) has been tested against the applicable ASTM standards listed above, and meet the requirements set forth in those standards.

There is no different between the proposed device and the predicate with respect to performance standard and technological characteristics.

The predicate device was tested for nine drugs, while proposed device tested for 15 drugs. Respective drug's permeation result is shown in Indication for Use of the proposed device. The different in labeling (with additional drugs tested, exceed ASTM D6978-05 requirements), and in Indications for Use (with permeation results added) does not affect the safety and effectiveness of the proposed device.

9.0 Substantial Equivalent Based on Assessment of Clinical Performance Data

Clinical data is not needed for market cleared examination gloves.

10.0 Conclusion

It can be concluded that the Powder Free Latex Patient Examination Glove, Blue, Tested for Use with Chemotherapy Drugs, with Protein Content Labeling Claim (Contains 50 Micrograms per dm^2 of glove or Less of Water Extractable Protein), is as safe and effective as, the current legally marketed device identified in this 510(k) summary.

The Substantial Equivalent Comparison Table below outlines the similarity, and/or differences between the proposed device and the predicate device for the substantial equivalent determination.

The gloves are Substantial Equivalent to predicate device cleared under 510(k) K083409.

Substantial Equivalent Comparison Table

Characteristics	**Predicate Device** K083409, Powder Free Blue Latex Patient Examination Glove, Tested for use with Chemotherapy Drugs with a Protein Content Label Claim (≤50 ug/dm^2 per glove of Extractable Protein)	**Proposed Device** Powder Free Latex Patient Examination Glove, Blue, Tested for Use with Chemotherapy Drugs, with Protein Content Labeling Claim (Contains 50 Micrograms per dm^2 of glove or less of Water Extractable Protein)
Device Description/ Regulation Number	Patient Examination Glove/ 21 CFR Part 880.6250	Substantial Equivalent
Product Code	80 LYY, 80 LZC	Substantial Equivalent
Intended Use	Intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.	Substantial Equivalent

Characteristics	**Predicate Device** K083409, Powder Free Blue Latex Patient Examination Glove, Tested for use with Chemotherapy Drugs with a Protein Content Label Claim (≤50 ug/dm^2 per glove of Extractable Protein)	**Proposed Device** Powder Free Latex Patient Examination Glove, Blue, with Protein Content and Chemotherapy Drugs Labeling Claim (Contains 50 Micrograms per dm^2 of glove or less of Water Extractable Protein)
Indications for Use	The powder free chemotherapy examination glove is a specialty medical. glove which is a disposable device intended for medical purposes that is worn on the examiner's hand or forefinger to prevent contamination between examiner and patient bodily fluids, waste and environment. Tested for use with chemotherapy drugs. Tested chemotherapy drugs are as follows [Cyclophosphamide, Carmustine, Thio-Tepa, Dacarbazine, Doxorubicin Hydrochloride, 5-Fluorouracil, Cisplatin, Etoposide, and Paclitaxel] **Warning: Do not use gloves with Thio-tepa and Carmustine.**	A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. This glove has been tested for use with specific chemotherapy drugs listed below. Chemotherapy Drug Permeation (Minimum Breakthrough Detection Time in Minutes) **Carmustine (3.3 mg/ml) 15.4** Cisplatin (1.0 mg/ml) >240 Cyclophosphamide (20.0 mg/ml) >240 Cytarabine (100 mg/ml) >240 Dacarbazine (DTIC) (10.0 mg/ml) >240 Doxorubicin Hydrochloride (2.0 mg/ml) >240 Etoposide (20.0 mg/ml) >240 Fluorouracil (50.0 mg/ml) >240 Ifosfamide (50.0 mg/ml) >240 Methotrexate (25 mg/ml) >240 Mitomycin C (0.5 mg/ml) >240 Mitoxantrone (2.0 mg/ml) >240 Paclitaxel (Taxol) (6.0 mg/ml) >240 **Thiotepa (10.0 mg/ml) 30.6** Vincristine Sulfate (1.0 mg/ml) >240 **Please note that the following drugs - Carmustine and Thiotepa have extremely short permeation times of 15.4 and 30.6 minutes, respectively.**
Design	Ambidextrous, in different sizes per ASTM D3578 dimension requirement.	Substantial Equivalent

Characteristics	**Predicate Device** K083409, Powder Free Blue Latex Patient Examination Glove, Tested for use with Chemotherapy Drugs with a Protein Content Label Claim (≤50 ug/dm^2 per glove of Extractable Protein)	**Proposed Device** Powder Free Latex Patient Examination Glove, Blue, with Protein Content and Chemotherapy Drugs Labeling Claim (Contains 50 Micrograms per dm^2 of glove or less of Water Extractable Protein)
Materials	Natural Rubber Latex	Substantial Equivalent
Color	Blue	Substantial Equivalent
Performance I. Sterility II. Freedom from holes III. Dimension IV. Physical Properties V. Powder Free Residue VI. Protein Content	 Not Applicable (Non-Sterile) Passes at AQL 1.5 Meets ASTM D3578 Meets ASTM D3578 Meets ≤ 2 mg/glove Meets ≤ 50 µg/dm^2	 Substantial Equivalent Passes at AQL 1.5 (Substantial Equivalent) Meets ASTM D3578 (Substantial Equivalent) Meets ASTM D3578 (Substantial Equivalent) Meets ≤ 2 mg/glove (Substantial Equivalent) Meets ≤ 50 µg/dm^2 (Substantial Equivalent)
Single Use	Yes	Substantial Equivalent
Biocompatibility Test	Passes i. Primary Skin Irritation Test ii. Dermal Sensitization Test	 Substantial Equivalent Substantial Equivalent
Packaging	Packed in Dispenser Boxes	Substantial Equivalent
Labeling Claim	i. With Extractable Protein Content Labeling Claim ii. Chemotherapy Drugs Labeling Claim per ASTM D6978-05	Substantial Equivalent

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 5, 2013

Ms. Rosnita Maodin
Quality Assurance Manager
Top Calibre Sdn Bhd
1-1, 2, Jalan Setia Prima U13/S
Setia Alam, Seksyen U13
Shah Alam, Selangor
Malaysia 40170

Re: K123819
Trade/Device Name: Powder Free Latex Patient Examination Glove, Blue Tested for Use with Chemotherapy Drugs, with Protein Content Labeling Claim (Contains 50 Micrograms per dm^2 of glove or Less of Water Extractable Protein)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYY, LZC
Dated: January 30, 2013
Received: February 4, 2013

Dear Ms. Moadin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K123819

Indications for Use

510(k) Number (if known): K123819

Device Name: Powder Free Latex Patient Examination Glove, Blue
Tested for Use with Chemotherapy Drugs, with Protein Content labeling Claim
(Contains 50 Micrograms per dm^2 of glove or Less of Water Extractable Protein)

Indications for Use:

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Please note that the following drugs - Carmustine and Thiotepa have extremely short permeation times of 15.4 and 30.6 minutes, respectively

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use X (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office Of Device Evaluation (ODE)

Elizabeth F Claverie
2013.03.05 16:12:07 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K123819